



PTO/SB/08a (05-03)

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	09/977,865		
		Filing Date	October 15, 2001		
		First Named Inventor	J. Kevin DONAHUE		
		Art Unit	1636		
		Examiner Name	K. Katcheves		
Sheet	1	of	3	Attorney Docket Number	001107.00449

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
✓		2002/0094326 A1	07/18/2002	Donahue et al.	
✓		6,100,270	08/08/2000	Campbell	

FOREIGN PATENT DOCUMENTS						
Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
✓		WO 96/16657	06/06/1996	Campbell		
✓		WO 99/19792	04/22/1999	Lawrence		
✓		WO 99/31982	07/01/1999	Stedman		

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✓		Lamping, K. et al., "Agonist-specific impairment of coronary vascular function in genetically altered, hyperlipidemic mice," <i>Am. J. of Phys.</i> , (April 1999), pp. R1023-R1029, Vol. 276, no. 4	
✓		Kuwahara, A. et al., "5-HT activates nitric oxide-generating neurons to stimulate chloride secretion in guinea pig distal colon," <i>Am. J. Phys.</i> , (October 1998), pp. G829-G834, Vol. 275, no. 4	
✓		Frieden, M. et al., "Effect of 5-hydroxytryptamine on the membrane potential of endothelial and smooth muscle cells in the pig coronary artery," <i>British Journal of Pharmacology</i> , (1995), pp. 95-100, Vol. 115, no. 1	
✓		Reiser, G., "Nitric oxide formation caused by calcium release from internal stores in neuronal cell line in enhanced by cyclic amp," <i>European Journal of Pharmacology Molecular Pharmacology Section</i> , (1992), pp. 89-93, Vol. 9, no. 1	
✓		Katz, S. et al., "Acute type 5 phosphodiesterase inhibition with sildenafil enhances flow-mediated vasodilation in patients with chronic heart failure," <i>Journal of the American College of Cardiology</i> , (September 2000), pp. 845-851, Vol. 36, No. 3	

Examiner Signature	<i>Kristina Katcheves</i>	Date Considered	8/5/05
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W		Lai, N.C. et al., "Sodium nitroprusside facilitates intracoronary gene transfer in pigs," <i>Faseb Journal</i> , (March 2001), p. A100, Vol. 15, No. 4	
f		Bilbao, R. et al., "A blood-tumor barrier limits gene transfer to the experimental liver cancer: The effect of vasoactive compounds," <i>Gene Therapy</i> , (November 2000), pp. 1824-1832, Vol. 7, no. 21	
		Corbin, J.D., et al., "Pharmacology of Phosphodiesterase-5 Inhibitors," <i>IJCP</i> , (July/August 2002), pp. 453-459, Vol. 56, No. 6	
		Eardly, I. et al., "Tadalafil (Cialis) for Men with Erectile Dysfunction," <i>IJCP</i> , (May 2002), pp. 300-304, Vol. 56, No. 4	
V		Donahue, J.K. et al., "Ultrarapid, highly efficient viral gene transfer to the heart," <i>PNAS</i> , (April 1997), pp. 4664-4668, Vol. 94	

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K		Donahue, J.K. et al., "Acceleration of widespread adenoviral gene transfer to intact rabbit hearts by coronary perfusion with low calcium and serotonin," <i>Gene Therapy</i> , (1998), pp. 630-634, Vol. 5	
		Hetman, J.M. et al., "Cloning and characterization of PDE7B a cAMP-specific phosphodiesterase," <i>PNAS</i> , (January 2004), pp. 472-476, Vol. 97, No. 1	
		Nagata, K. et al., "Phosphodiesterase Inhibitor-mediated Potentiation of Adenovirus Delivery to Myocardium," <i>J. Mol. Cell Cardiol.</i> , (2001), pp. 575-580, Vol. 33	
		Sung, B. et al., "Structure of the catalytic domain of human phosphodiesterase 5 with bound drug molecules," <i>Nature</i> , (September 2003), pp. 98-102, Vol. 425	
		Lenhart, S.E. et al., "Preservation of myocardial function after adenoviral gene transfer in isolated myocardium," <i>Am. J. Physiol. Heart Circ. Physiol.</i> , (2000), pp. H986-H991, Vol. 279	
		Rotella, D., "Phosphodiesterase 5 Inhibitors: Current Status and Potential Applications," <i>Nature</i> , (September 2002), pp. 674-682, Vol. 1	
		Soderling, S.H. et al., "Cloning and characterization of a cAMP-specific cyclic nucleotide phosphodiesterase," <i>PNAS</i> , (July 1998), pp. 8991-8996, Vol. 95	
		Barr, E. et al., "Efficient catheter-mediated gene transfer into the heart using replication-defective adenovirus," <i>Gene Therapy</i> , (January 1994), pp. 51-8, Vol. 1, No. 1 (Abstract Only)	
		Ding, Z. et al., "A minimally invasive approach for efficient gene delivery to rodent hearts," <i>Gene Therapy</i> , (February 2004), pp. 260-265, Vol. 11, No. 3 (Abstract Only)	
		Inoue H. et al., "T-1032, a novel specific phosphodiesterase type 5 inhibitor, increases venous compliance in anesthetized rats," <i>Eur J. Pharmacol.</i> , (June 2001), pp. 109-114, Vol. 422, No. 1-3 (Abstract Only)	
K		Takagi, M. et al., "Pharmacological profile of T-1032, a novel specific phosphodiesterase type 5 inhibitor, in isolated rat aorta and rabbit corpus cavernosum," <i>Eur J. Pharmacol.</i> , (January 2001), pp. 161-168, Vol. 411, No. 1-2 (Abstract Only)	

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